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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,383	06/27/2005	Ulrik Darling Larsen	ALB.018	5689

20987 7590 01/22/2010

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EXAMINER	
FRITCHMAN, REBECCA M	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
01/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,383	LARSEN ET AL.	
	Examiner	Art Unit	
	REBECCA FRITCHMAN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action
Summary

This is the initial Office action based on the 10517383 application RCE attorney remarks filed 11/04/2009.

Claims 22-48 are pending and have been fully considered.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. **Claims 22, 37, & 39-46 are rejected under 35 U.S.C. 102(b) as being anticipated by BERNDTSSON in US 6387328.**

With respect to Claim 22, BERNDTSSON teaches of a cartridge for counting and discriminating a plurality of types of blood cells in a blood sample (column 1, lines 11-14, & column 3, lines 28-31) in one counting operation(column 3, lines 28-31, column 4, lines 13-14), comprising a housing with characterizing particles suspended in a liquid sample(liquid storage chamber)(column 3, lines 28-31, column 3, lines 39-48). Specifically, BERNDTSSON et al. teach of cylinder 61 in Figure 2 being the first liquid storage chamber, cylinder 44 being the first mixing chamber, capillary and blood recess 62 as the first collection chamber, electrodes 65 & 66 being the first cell characterization means, 55 as the bore, and valve 50 as the first sampling member BERNDTSSON et al. also teach of the first orifice being stradled by two electrodes(65 & 66)(the first half of the capillary channel is part of the mixing

chamber, while the last half is part of the collection chamber(column 4, lines 4-15). It appears from the instant application (Figure 3 below) requires a capillary or channel leading to and downstream from the orifice.

3/9

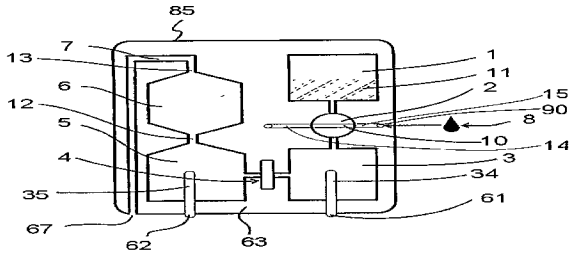

Fig. 3

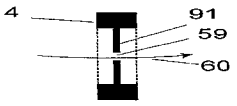

Fig. 4

With respect to Claim 37, BERNDTSSON teaches of a housing with characterizing particles suspended in a liquid sample (reagent storage chamber) (column 3, lines 28-31, column 3, lines 39-48).

With respect to Claim 39, BERNDTSSON teaches of a mixing member being positioned in the mixing chamber (column 4, lines 66-67, & column 5, lines 1-17).

With respect to Claims 40 & 41, BERNDTSSON teaches of the use of a sensor for photometric measurement (column 6, lines 21-22).

With respect to Claims 42-46, BERNTSSON teaches of the hole for passage of blood cells having a diameter of 80 micrometers. It would be obvious

to one of ordinary skill in the art to optimize the size of this diameter for the passage of cells.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 23-36, & 47-48 are rejected under 35 U.S.C. 103(a) as being obvious over BERNDTSSON in US 6387328 in view of MALLINCKRODT in EP 1182457(as cited on IDS dated 02/16/2005)**

With respect to Claim 23, see above rejection of Claim 22. MALLINCKRODT teaches of the lysing reagent containing a surfactant (sodiumdodecylsulfate) (Page 11, Table 1). It would have been obvious to use the lysing reagent of MALLINCKRODT in one of the liquid reagent containers of BERNDTSSON if one wanted to count only white blood cells due to known problems and the need in the art for an aperture device in which different types of cells can be counted directly (MALLINCKRODT, paragraphs 0006 & 0007).

With respect to Claim 24, MALLINCKRODT teaches of the lysing reagent containing a surfactant (sodiumdodecylsulfate) (Page 11, Table 1).

MALLINCKRODT does not teach of the use of saponin, however, saponin is an equivalent chemical for its use in the lysing agent as a surfactant.

With respect to Claim 25, MALLINCKRODT teaches of lysing reagent containing a quaternary ammonium salt (Page 11, Table 1).

With respect to Claims 26-28, MALLINCKRODT teaches of the use of isotonic solutions to be used with the lysing agent to minimize debris from red blood cells (paragraph 0022, and page 11, table 1).

With respect to Claim 29, MALLINKRODT teaches of the use of a urea compound in the dilutent to be mixed with the lysing reagent (Claim 10).

With respect to Claim 30, MALLINKRODT teaches of the use of cyanide for converting the product to a product suitable for spectrophotometric analysis (paragraph 0066).

With respect to Claim 31, MALLINKRODT teaches of the use of inorganic salts (paragraph 0055 7 0056).

With respect to Claim 32, MALLINKRODT teaches of the lysing reagent comprising hexadecyltrimethyl-ammoniumhalogenide (paragraph 0061).

With respect to Claim 33, MALLINKRODT teaches of counting the lysed/strippedblood sample (stripped-the blood cells will be reduced in size) (Claims 12 & 14).

With respect to Claim 34, MALLINKRODT teaches of the blood cell types being monocytes and granulocytes (paragraph 0077).

With respect to Claims 35 & 36, BERNDTSSON and MALLINKRODT disclose the claimed invention except for the duplication of the mixing chamber,

collection chamber, second orifice, second mixing chamber system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to duplicate these parts, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86, USPQ 70

With respect to Claims 47 & 48, MALLINKRODT teaches of the blood cell types being monocytes and granulocytes (paragraph 0077).

3. **Claim 38 is rejected under 35 U.S.C. 103(a) as being obvious over BERNDTSSON in US 6387328 in view of SEYMOUR in US 5393496.**

With respect to Claim 38, BERNDTSSON teaches of a cartridge for counting and discriminating a plurality of types of blood cells in a blood sample (column 1, lines 11-14, & column 3, lines 28-31). BERNDTSSON does not teach of a breakable seal separating the reagent chamber from the mixing chamber. SEYMOUR et al. do teach of a breakable seal in a sample testing device in which the seal breaks and allows the mixture of the buffering solution and the sample to flow. It would have been obvious to combine the breakable seal of SEYMOUR with BERNDTSSON due to prior teaching of sampling devices in which after the specimen is obtained, the specimen collector is forced through the seal into a liquid preservative(column 2, lines 10-15).

In alternative to the 102(b) rejection above:

4. **Claims 22, 37, & 39-46 are rejected under 35 U.S.C. 103(a) as unpatentable over BERNDTSSON in US 6387328 in view of DOUTRE in EP 193394 on IDS dated 06/30/2009.**

With respect to Claim 22, BERNDTSSON teaches of a cartridge for counting and discriminating a plurality of types of blood cells in a blood sample (column 1, lines 11-14, & column 3, lines 28-31) in one counting operation(column 3, lines 28-31, column 4, lines 13-14), comprising a housing with characterizing particles suspended in a liquid sample(liquid storage chamber)(column 3, lines 28-31, column 3, lines 39-48). Specifically, BERNDTSSON et al. teach of cylinder 61 in Figure 2 being the first liquid storage chamber, cylinder 44 being the first mixing chamber, capillary and blood recess 62 as the first collection chamber, electrodes 65 & 66 being the first cell characterization means, 55 as the bore, and valve 50 as the first sampling member BERNDTSSON et al. also teach of the first orifice being stradled by two electrodes(65 & 66)(the first half of the capillary channel is part of the mixing chamber, while the last half is part of the collection chamber(column 4, lines 4-15). BERNSTSSON et al. teach of the electrodes being in the channel/ chambers first mixing chamber and the first collection chamber. In the case that the instant invention requires the electrodes to be in leading and downstream positions across a wall separating the first mixing chamber and the first collection chamber which accommodates the orifice, such is known in the art as taught by, DOUTRE, which teaches an apparatus for studying particles in an electrically

conducting fluid including an aperture with a pair of electrodes (Claim 1, Figure 1, 14 & 16) which are disposed on opposite sides of the wall. It would be obvious to one of ordinary skill to combine the invention of BERNDTSSON with the electrodes of DOUTRE to establish a current path between the through the fluid and passing through the aperture to allow for improved characterization of the cells (Claim 1).

With respect to Claim 37, BERNDTSSON teaches of a housing with characterizing particles suspended in a liquid sample (reagent storage chamber) (column 3, lines 28-31, column 3, lines 39-48).

With respect to Claim 39, BERNDTSSON teaches of a mixing member being positioned in the mixing chamber (column 4, lines 66-67, & column 5, lines 1-17).

With respect to Claims 40 & 41, BERNDTSSON teaches of the use of a sensor for photometric measurement (column 6, lines 21-22).

With respect to Claims 42-46, BERNTSSON teaches of the hole for passage of blood cells having a diameter of 80 micrometers. It would be obvious to one of ordinary skill in the art to optimize the size of this diameter for the passage of cells.

Claim Rejections - 35 USC § 103

5. **Claims 23-36, & 47-48 are rejected under 35 U.S.C. 103(a) as being obvious over BERNDTSSON in US 6387328 in view of DOUTRE in EP 193394 on IDS dated 06/30/2009 and in further view of MALLINCKRODT in EP 1182457(as cited on IDS dated 02/16/2005)**

With respect to Claim 23, see above rejection of Claim 22. MALLINCKRODT teaches of the lysing reagent containing a surfactant (sodiumdodecylsulfate) (Page 11, Table 1). It would have been obvious to use the lysing reagent of MALLINCKRODT in one of the liquid reagent containers of BERNDTSSON if one wanted to count only white blood cells due to known problems and the need in the art for an aperture device in which different types of cells can be counted directly (MALLINCKRODT, paragraphs 0006 & 0007).

With respect to Claim 24, MALLINCKRODT teaches of the lysing reagent containing a surfactant (sodiumdodecylsulfate) (Page 11, Table 1). MALLINCKRODT does not teach of the use of saponin, however, saponin is an equivalent chemical for its use in the lysing agent as a surfactant.

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With respect to Claim 33, MALLINKRODT teaches of counting the lysed/strippedblood sample (stripped-the blood cells will be reduced in size) (Claims 12 & 14).

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With respect to Claims 47 & 48, MALLINKRODT teaches of the blood cell types being monocytes and granulocytes (paragraph 0077).

6. **Claim 38 is rejected under 35 U.S.C. 103(a) as being obvious over BERNDTSSON in US 6387328 in view of DOUTRE in EP 193394 on IDS dated 06/30/2009, And in further view of SEYMOUR in US 5393496.**

With respect to Claim 38, see above rejection of claim 22. SEYMOUR et al. do teach of a breakable seal in a sample testing device in which the seal breaks and allows the mixture of the buffering solution and the sample to flow. It would have been obvious to combine the breakable seal of SEYMOUR with BERNDTSSON due to prior teaching of sampling devices in which after the specimen is obtained, the specimen collector is forced through the seal into a liquid preservative(column 2, lines 10-15).

Response to Arguments

The examiner would like to point out that there were no new grounds of rejection in the interview. The examiner merely further clarified her position by describing the Berndtsson reference.

Also, examiner acknowledges receipt of IDS dated 06/30/2009. The documents listed therein have been considered and will be cited of record in the present application.

BERNDTSSON teaches of a cartridge for counting and discriminating a plurality of types of blood cells in a blood sample (column 1, lines 11-14, & column 3, lines 28-31) in one counting operation(column 3, lines 28-31, column 4, lines 13-14), comprising a housing with characterizing particles suspended in a

liquid sample(liquid storage chamber)(column 3, lines 28-31, column 3, lines 39-48). Specifically, BERNDTSSON et al. teach of cylinder 61 in Figure 2 being the first liquid storage chamber, cylinder 44 being the first mixing chamber, capillary and blood recess 62 as the first collection chamber, electrodes 65 & 66 being the first cell characterization means, 55 as the bore, and valve 50 as the first sampling member BERNDTSSON et al. also teach of the first orifice being stradled by two electrodes(65 & 66)(the first half of the capillary channel is part of the mixing chamber, while the last half is part of the collection chamber(column 4, lines 4-15).

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone

number is (571)270-5542. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim, Vickie can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

R.F.